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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,730	06/08/2000	Dale C. Kenison	99,267	9108

26263 7590 06/26/2003

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EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09 589730

Applicant(s)

Kenison et al

Examiner

McLewy

Group Art Unit

16/6

17

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 5/13/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 5-9, 13-32, 41-47 & 49-64 is/are pending in the application.
- Of the above claim(s) 5-9, 13-32, 41-47, 52, 55, 59 & 63 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 42-51, 53, 54, 56-58, 60-62 & 64 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 5-9, 13-32, 41-47 & 49-64 are subject to restriction or election requirement.

## Applicable Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Receipt is acknowledged of Declaration, time RCE and Amendment, of 5/12/03 each, respectively.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5-9, 13-32, 41-47, 52, 55, 59, 63 stand are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Claims 49-51, 53, 54, 56-58, 60-62 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites an implant, presumably A, or ONE device, comprising at least 2 discrete pellets. Absent any connecting material, means or further limitation, it is unclear if the 2 pellets are in fact connected, ~~just~~ positioned, or otherwise associated or combined in some manner to form, or as a portion of, the otherwise minimally identified implant. The 2 pellets can be considered as individual implants separated not only in space, but also in time.

Claims 49-51, 54, 58, 61, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al '98 in view of Ivy et al 4670249 and Shih- WO 0/25743.

Johnson enhanced Lamb growth, with an implant of trenbolone acetate and.

Estradiol however, it is not clear implant *had 2 separate pellets, n.c.*

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Ivy shows separate or combination as equivalent growth hormone/growth promoter Zeranol, in Sheep implants (col. 3, lines 49 – line 23, col. 4), of pellet form for long action. Any anabolic growth hormone is useful (col. 3, line 35-43), although Ivy didn't use Trenbolone or estradiol. Smith did, as equivalents for estradiol and trenbolone (p.7, top). Ivy uses both Immediate release (p. 7, line 9+) and controlled release (line 18+, p. 7), biodegradable implantable pellets (p.8, line 15). The pellets are administered separately from the same device (p.11, Last paragraph). See claim 7 – The agents are different; see claim 8, see claim 10 dosages are shown at p. 16 = 12 – 178 mg.

Thus, it would be obvious to one of ordinary skill in the art desiring to utilize implants of anabolic agents of Johnson, in order to enhance sheep growth to modify the delivery as shown equivalently effective by Ivy, with separate fast and slow pellets of SHIH. SHIH also shows equivalence of the use of combinations, inclusive of the Johnson, IVY, and Instant agents, all in the art of animal growth enhancement.

Applicant does not have nor provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed. The declaration is directed to different combination than those elected, and the results, in accord with the cited art, are expected.

The selection of each ingredient is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature of each ingredient to optimize the effects desired.


There is no unusual and/or unexpected results obtained since the prior art is well aware of the use and the use ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant's arguments filed 5/12/03 have been fully considered but they are not persuasive. Applicant's arguments are persuasive, in view of amendments, but **u**pdated search and consideration finds the instant claims met by prior art, and open to multiple interpretation. The elected species, however is not seen as differentiated from other estradiol forms and we would expect 10-100 mg melengesterol to be as effective as the prior art combinations, absent any data to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703)308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
NEIL S. LEVY  
PRIMARY EXAMINER